

**STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES**

MEDICAID 1115 RESEARCH AND DEMONSTRATION WAIVER APPLICATION

**A PHARMACEUTICAL BENEFIT
FOR NEW JERSEY'S LOW-INCOME SENIORS AND DISABLED**

MARCH 28, 2002

I. Executive Summary

The State of New Jersey, through its Department of Human Services (DHS), requests that the Center for Medicaid State Operations (CMSO) approve a waiver under the demonstration project authority of Section 1115 of the Social Security Act for New Jersey's Pharmaceutical Assistance to the Aged and Disabled (PAAD) program, administered by New Jersey's Department of Health and Senior Services (DHSS). New Jersey is seeking the waiver for people with incomes at or below 200% of the Federal Poverty Level (FPL). This waiver is sought to enable New Jersey to maintain the PAAD program benefits, as well as Senior Gold, an additional State-funded program serving elders with incomes up to 300% FPL. The PAAD program is currently available to State residents aged 65 or older or to disabled with incomes up to 222% of FPL, if single, and 202% of FPL, if married. Absent approval of this waiver, New Jersey anticipates substantial cuts in the appropriations to the PAAD program, which will result in a significant reduction in pharmacy benefits.

PAAD had its origins in a more limited program established in 1975 and assumed its current form with legislative amendments first introduced in 1982. Since that time, New Jersey has spent over \$4 billion in direct program benefits, a financial burden borne entirely by the State. However, a confluence of factors – a worsening economy, consistent double digit price increases for pharmaceuticals, competing budget priorities and the growing enrollment in the PAAD and Senior Gold programs – now threatens New Jersey's position as administrator of the most generous pharmacy assistance program in the nation. The State of New Jersey is confronted by a \$8.2 billion gap between resources and spending needs over the 18 months spanning January 1, 2002 through June 30, 2003, which represents the largest percentage shortfall of any State in the country. The spending proposed by Governor McGreevey will be limited to 1.5% while PAAD costs are expected to grow 21% due to increasing costs and caseload for the PAAD program. As a result, the State is considering proposals to radically restructure the PAAD program including: implementation of an asset test, increased co-payments and other cost-sharing measures, a reduction in reimbursement rates to pharmacy providers and capping program participation. In addition, New Jersey may also be faced with reducing benefits in other health care programs such as FamilyCare. Such changes, if implemented, will inevitably result in an increase in the number of elderly and disabled who lack basic pharmacy health coverage with its attendant adverse impact on health care costs and outcomes, including an increase in the nursing home population.

New Jersey's PAAD and Senior Gold programs provide vital financial assistance with the cost of prescription medications to eligible New Jersey residents with limited incomes, who are over the age of 65 or who are at least eighteen years of age and are receiving Social Security Title II disability benefits. The Drug Formulary for these programs have adopted New Jersey's current Medicaid State Plan formulary, which is in conformity with the Omnibus Budget Reconciliation Act of 1990.

PAAD, which serves a population that is almost exclusively Medicare eligible, provides prescription drug coverage to approximately 199,000 beneficiaries. Senior Gold, New Jersey's recently expanded pharmacy benefit program, which includes higher income residents, covers 26,000 beneficiaries. Thus,

the State-only funded pharmaceutical programs administer prescription benefits to more than 225,000 residents. In the absence of federal assistance, State costs in fiscal year 2003 would total \$460 million. This is an increase of \$139 million compared to fiscal year 2000. Through these programs New Jersey provides over 8.9 million prescriptions annually at an average of 32 per year per eligible person.

Research has demonstrated that prescription drugs are cost-effective because they reduce hospital and nursing home utilization and expenditures. These savings relate not only to the preventative nature of some pharmaceuticals, but also to the fact that inadequate coverage of this primary care benefit causes millions of low-income seniors to reduce their use of clinically essential medications, increasing hospital and nursing home admissions, and costing more to the health care system in the aggregate.

New Jersey's State-only funded pharmacy programs currently provide (and have historically provided) significant savings to the federally funded Medicare Program and the federal-State funded Medicaid program. Providing beneficiaries with life sustaining and enhancing pharmaceuticals reduces the incidents of Medicare/Medicaid funded institutional care. Moreover, the provision of this pharmaceutical assistance helps to reduce Medicaid-funded long-term care admissions and diminish the rate of enrollment in Medicaid through spend-down. It is appropriate, therefore, for the Federal Government to help ensure the continuation of PAAD by participating in the funding of this cost-effective and beneficial program through a waiver approval. Over the life of the waiver, savings realized by this Demonstration waiver can be used to support the State-funded pharmacy programs for PAAD members above the 200% FPL, as well as the Senior Gold program.

The prescription drug benefit will mirror the pharmaceutical requirements of the State's current Medicaid State Plan, which covers all products that are required under the Omnibus Budget Reconciliation Act of 1990. This comprehensive pharmaceutical benefit package covers all disease states.

DHS proposes to demonstrate that continuing to provide comprehensive pharmacy benefits to this population will provide the following benefits:

- It will maintain the health status of elderly and disabled individuals at an optimal level by providing access to clinically essential medications.
- It will prevent an increase in costly admissions to hospitals and long-term care facilities, thereby reducing health care costs for Medicare beneficiaries.
- It will delay senior / disabled eligibility for the State Medicaid program by preventing a premature achievement of the "spend-down threshold" by this population, who would then become eligible for the full panoply of Medicaid services.
- It will avoid and / or delay admissions to long-term care facilities by this population who are likely to become permanently reliant on public funding.

New Jersey anticipates that prescription drug coverage for the elderly and disabled will continue to require additional public funding as more elderly and individuals with qualified disabilities enroll in the PAAD program and as the cost of prescription drugs continue to rise disproportionately to other health care costs. Even though DHSS projects a total enrollment of nearly 250,000 members along with a projected cost in excess of \$800 million dollars by SFY07, New Jersey plans to take drastic budgetary measures to address its fiscal crisis if the State is unable to obtain approval of this pharmacy waiver. As previously stated, the New Jersey legislature may reduce the available program costs to levels that can be supported by the Casino Revenue Fund. State costs would necessitate the implementation of more stringent eligibility requirements such as an asset test, a cap on enrollment, and an increase in client out-of-pocket costs. Therefore, New Jersey is submitting this 1115 demonstration waiver to obtain Federal

funding in order to sustain the pharmacy assistance program and to continue to fund the existing level of pharmacy benefits and provide coverage for higher income PAAD members above the 200% FPL. Over the life of the waiver, New Jersey would use the savings to fund its higher income PAAD population and the Senior Gold program.

II. Proposed Pharmacy Waiver Program Design

A. Eligibility Requirements: State Medicaid programs may have two types of eligibility categories: categorically needy and medically needy. Both categories are established under the Social Security Act. Certain groups, such as pregnant women or the elderly, are considered categorically eligible if they also meet income criteria based on the FPL. “Medically needy” eligibles are those that would be categorically needy except for their slightly higher income and resources, but who cannot afford to pay their medical bills. For the purposes of this waiver, all individuals will be considered categorically needy and eligible for prescription drug services if they meet the following requirements:

- 1) The individual is a New Jersey resident, legally domiciled within the State (of N.J.)...” immediately preceding the date of application for inclusion in the PAAD Program.
- 2) The individual has an income at or below 200% FPL.
- 3) The individual is at least 65 years of age **OR** at least 18 years of age and receiving Social Security Disability benefits. *
- 4) The individual must not have a health insurance or retirement benefits that provide prescription coverage equal to or better than PAAD. However, the individual is eligible if the health insurance or retirement plan offers limited or partial prescription drug insurance.

* Note: If the individual is under age 65 and receiving Social Security benefits that are not based upon his/her disability, the individual is not eligible.

B. Application Process for Pharmacy Waiver Benefits: The application process includes all activity relating to a request for eligibility determination. It begins with the receipt by DHSS of an eligibility application and continues in effect until there is an official disposition of the request by DHSS. The PAAD eligibility unit uses the on-line State Verification Exchange System (SVES) to request and retrieve information from Social Security. Through the SVES system, staff has the ability to verify age, address, and Social Security entitlement and benefit amount, thereby eliminating the time-consuming need to return applications to request this specific information. The processing of an application is normally completed within a 30-day period. Because the eligibility requirements for the proposed 1115 waiver program are the same as those for the current PAAD, DHSS plans to automatically enroll all individuals, currently covered by PAAD, in the waiver program.

C. Benefits: The waiver program pharmacy benefit will be as comprehensive as that provided in the current New Jersey Medicaid State Plan, which covers all products that are required under the Omnibus Budget Reconciliation Act of 1990 and all disease States.

D. Cost-Sharing

1. Annual Enrollment Fees: There is no annual enrollment fee. However, if the federal waiver is not approved, an annual enrollment fee may be implemented.

2. Co-payments: Participants in this program will share the costs of waiver program benefits. Cost-sharing will include a co-payment in the amount of \$5.00, which must be paid by each PAAD beneficiary (and is not reimbursable) to the pharmacy toward the cost for each prescription for a legend drug and/or insulin, insulin syringes, insulin needles, and certain diabetic testing materials. Generic equivalents are automatically substituted for brand name drugs, unless the physician indicates that the brand name drug is

medically necessary. In that case, a participant will pay the \$5.00 co-payment only. In an instance where a brand name drug is not medically necessary, participants pay the \$5.00 co-payment plus the difference between the cost for the brand name and the generic prescription. If the federal waiver is not approved the co-payment may be increased and the reimbursement policies to pharmacies may be changed. The PAAD program is responsible to pay the difference between the co-payment and the “reasonable cost” of a prescription drug. “Reasonable cost” means the maximum allowable cost plus a dispensing fee.

3. *Future Adjustments to Cost-Sharing:* DHS proposes that it be granted flexibility under the waiver to modify, within specified limits, cost-sharing requirements during the term of the 1115 Research and Demonstration Waiver program to control program costs. Within the per prescription co-payment limit specified above, DHS may institute a co-payment structure to create an incentive for providers to prescribe drugs that are medically and economically appropriate.

E. Benefit Management Strategies: The following types of drug utilization are currently operating and will continue under the waiver:

1. *Prospective Drug Utilization Review (ProDUR) Program:* DHS and DHSS have established a ProDUR program to assist pharmacies with monitoring drug utilization by PAAD beneficiaries. At the POS, an automated real-time concurrent DUR screening is performed.

2. *Retrospective DUR:* In accordance with requirements imposed by OBRA, PAAD has implemented a Retrospective Drug Utilization Review (RetroDUR) to review claims data in order to identify fraud, abuse, or inappropriate or medically unnecessary care resulting from physician prescribing patterns.

3. *Medical Exception Process (MEP), enhancing ProDur:* New Jersey has implemented a new State policy requiring pharmacists to comply with the MEP for certain pharmaceutical services. This process is for those services which exceed DUR standards recommended by the New Jersey Drug Utilization Review Board and approved by the Commissioners of Human Services and Health and Senior Services.

4. *Coordination with Other Medicaid Programs :* PAAD workers will do screening for Medicaid eligibility and referral to (or assistance in applying for) Medicaid in order to ensure Medicaid-eligible clients receive full coverage. PAAD staff and Ryan White staff are both housed in the Department of Health and Senior Services. Additionally, both the PAAD program and the Senior Gold program use the same claims processing system employed by the State Medicaid system.

5. *Recoveries and Liens:* PAAD seeks reimbursement for services through three types of recoveries:

- A. *Third Party Liability:*** PAAD beneficiaries who have equal or superior prescription coverage through another source are ineligible for PAAD. The program recoups approximately \$7-\$10 million per year in recoveries.
- B. *Drug Manufacturer Rebates:*** Firms must agree to provide rebates to the State in order for their drugs to be covered by PAAD. This ensures that PAAD receives a volume discount similar to that provided by manufacturers to other volume purchasers such as hospitals and HMOs.
- C. *Participant Recoveries:*** PAAD eligibility is based on anticipated income for the current year, allowing beneficiaries to receive benefits in the year they are needed. However, on the renewal application, the beneficiary must report both anticipated and prior year income. If prior year income verifies that the beneficiary received benefits incorrectly, the full amount of benefits received during the year are recovered. If an ineligible beneficiary refuses to pay, their State income and property tax rebates are withheld through the Set-Off of Individual Liability (SOIL) program until the balance owed is collected. The program collects approximately \$3 million per year in recoveries of incorrectly paid benefits.

6. PAAD's Medicare Recovery Initiative: Participating pharmacy providers must take part in the PAAD Medicare Recovery Initiative by enrolling as Medicare Part B suppliers pursuant to P.L.2001, c. 130, and authorize PAAD to act as their billing agent for claims that are covered under both PAAD and Medicare.

7. Quality Assurance: Operating policies have been established within DHSS to expedite the processing of applications and assure the maximum possible compliance with the standards set forth for the PAAD program. See N.J.A.C. 8:83-1.1 *et seq.* Additionally, DHSS, in conjunction with DHS, has the responsibility for monitoring providers participating in the PAAD program, verifying that claims submitted to the program by such providers are in compliance with program regulations, and investigating PAAD beneficiaries in matters involving potential fraud and / or abuse.

III. Waiver Program Implementation and Administration

A. Administering Agency: DHSS will administer the demonstration waiver through a memorandum of understanding with DHS. Portions of the program may be administered by private entities.

B. Financing: Prescription drug services under the 1115 waiver program will be funded jointly through State funds and matching federal monies. Costs of the program will be reduced by monies obtained from the PAAD drug rebate program. Moreover, NJ anticipates increased rebates if the waiver is approved as the drug rebates will be commensurate with rebates obtained by Medicaid.

C. Provider Network: The 1,700 pharmacies currently enrolled in PAAD program (99% of licensed pharmacies) will fill prescriptions for waiver program recipients as well. The pharmacies will be expected to enroll to become an eligible provider. A pharmacy, with a retail or institutional permit, may participate in the PAAD program as a provider of pharmaceutical services.

D. Implementation Schedule: DHS expects the waiver program to last for five years with an July 1, 2002 date of implementation. Since most of the program design features are already in place, DHSS is confident that the waiver program will be operational by the target date.

E. Early Termination of the Waiver Program

1.) State Right to Terminate or Suspend Demonstration: New Jersey reserves the right to suspend or terminate this demonstration in whole or in part at any time before the date of expiration. If the State chooses to terminate this demonstration before the expiration date, it will notify CMS in writing at least 30 days prior to terminating services to participants. If CMS or the State terminate the demonstration, the State will, at least 30 days prior to termination, notify participants of services of the actions it intends to take, notify them of the effective date of the action, and how the action will affect the participants.

2.) CMS Right to Terminate or Suspend Demonstration Operation: During demonstration operation, CMS may suspend or terminate FFP for any project in whole or in part at any time before the date of expiration, whenever it determines that the State has materially failed to comply with the terms of the project. The CMS will promptly notify the State in writing of the determination and the reasons for the suspension or termination. The effective date of such action shall not be fewer than 45 days from the date of notice. The State waives none of its rights under 42 CFR 430 to challenge CMS's finding that the State materially failed to comply. The CMS reserves the right to withhold waivers and authority for pending FFP for costs not otherwise matchable or to withdraw waivers or authority for costs not otherwise matchable at any time if it determines that granting or continuing the waivers or authority for cost not otherwise matchable would no longer be in the public interest. If the waiver or authority for costs not otherwise matchable is withdrawn, CMS will be liable only for normal close-out costs.

IV. Waivers Requested

This demonstration program requires waivers from Title XIX of the Social Security Act. Section 1115(a)(1) of the SSA permits the Secretary of the Department of Health and Human Services to waive compliance with any of the requirements of Section 1902 of the Social Security Act, which specify State Medicaid Plan requirements. Compliance may be waived to the extent and for the period necessary to carry out the demonstration project. Section 1115(a)(2) permits New Jersey to regard as expenditures under the State plan costs of the demonstration project that would not otherwise receive a federal match under section 1903 of the Social Security Act. These provisions allow the Secretary to waive existing program restrictions and provide expanded eligibility and/or services to individuals not otherwise covered by Medicaid. New Jersey requests that the Secretary waive the following Title XIX provisions:

- **Eligibility Income Standards Upper Limits.** New Jersey requests the Secretary to waive Sections 1902(l), 1902(m) and 1903(f) of the SSA and 42 CFR Section 435, all subparts. New Jersey seeks a waiver of coverage for mandatory groups and of the stated income maximums to expand eligibility for pharmaceuticals to non-categorical individuals, i.e., aged, blind and disabled (receiving SSA disability benefits) residing in the community with incomes equal to or less than 200% of the FPL.
- **Amount, Duration, and Scope of Services.** New Jersey requests the Secretary to waive Section 1902(a)(10)(B) of the SSA and 42 CFR Sections 440.230 through 440.250. These sections require the amount, duration, and scope of services be equally available to all recipients within an eligibility category and equally available to categorically eligible and medically needy recipients. New Jersey seeks a waiver of these provisions to offer a comprehensive drug benefit to the expanded population.
- **Co-payments.** New Jersey requests the Secretary to waive Section 1916 (a), (b) and (f) of the SSA that requires co-payments to be identical among all Medicaid recipients.
- **Retrospective Benefits.** New Jersey requests the Secretary to waive Section 1902(a)(34) of the SSA and 42 CFR 435.914 that require a State to retrospectively provide medical assistance for three months prior to the date of application in certain circumstances. New Jersey requests a waiver to establish the effective date for demonstration participants as the date of enrollment.
- **Eligibility Financial Requirements.** New Jersey requests the Secretary to waive Sections 1902(a)(17), 1902(a)(10)(A)(ii)(I) of the SSA and 42 CFR Part 435, Subparts G, H and I. These references establish standards for taking into account income or resources of individuals who are not receiving assistance under Medicaid-related Aid to Families with Dependent Children (AFDC) or Supplemental Security Income (SSI). All Medicaid/AFDC and SSI recipients are entitled to New Jersey Medicaid benefits. Individuals who are ineligible for Medicaid/AFDC or SSI benefits will be eligible for the demonstration program if they meet age, or disability, and income requirements; however, there will not be an asset test applied to this population. New Jersey requests to waive the standards for taking into account resources in determining eligibility for this demonstration project.
- **Administration.** New Jersey requests the Secretary to waive Section 1902(a)(5) of the SSA and 42 CFR 431.10. These sections prohibit the State from designating anyone other than the Title XIX Agency to determine eligibility.
- **Liens, adjustments and recoveries, and transfers of assets.** New Jersey requests that the Secretary waive Section 1917(b) of the SSA. This section requires the State to undertake estate

recoveries of correctly paid medical assistance on behalf of an individual under the State plan. Currently, such recoveries are prohibited by New Jersey Public Laws of 1983, chapter 371.

- **Expenditures.** New Jersey requests that, under the authority of Section 1115(a)(2) of the SSA, expenditures for the items identified below (which are not otherwise included as expenditures under Section 1903) be regarded as expenditures under New Jersey's Medicaid State Plan for the period of this demonstration:
 - Expenditures to provide and receive comprehensive pharmacy benefits to seniors age 65 and older and qualified disabled, equal of less than 200% of the federal poverty level.
 - Administrative Expenditures for demonstration participants including but not limited to determining eligibility, enrolling pharmacies, producing and distributing enrollment cards to program participants, responding to client inquiries, collecting third-party insurance information and evaluation and monitoring of this demonstration waiver.

New Jersey requests the right to consider other waivers to implement the proposed pharmacy program.

V. Program Implications for the Private Health Insurance Industry

The PAAD program has been designed to complement, rather than compete with, the private health insurance industry. The goal of the PAAD program is to provide public coverage to cover uninsured or to supplement inadequate private coverage. The consistent proportion of those members of PAAD who have other prescription drug coverage indicates that individuals are unlikely to obtain the PAAD prescription drug benefit in lieu of private insurance.

VI. Budget and Cost-Effectiveness Analysis (See attachments)

VII. Maintenance of Effort

New Jersey is facing imminent budget cuts for the PAAD program, absent the approval of this pharmacy waiver. Should the waiver be approved, however, the FFP will be used to maintain current eligibility and benefit levels. Although savings may be realized by the State, initially, the State anticipates an increase in State funds shall be demonstrated over the life of the waiver, 5 years. Assessments of maintenance of effort will be included in each annual report to CMS.

VIII. Program Evaluation and Monitoring

In New Jersey, as throughout the country, policymakers are confronted with a challenge to address the issues of cost, access and coverage of a pharmaceutical benefit. The implementation of this demonstration waiver provides an invaluable opportunity for State and federal policymakers to study a prescription drug program in terms of cost-sharing and other benefit design and its effect on the health and welfare of its recipients. The goal of this demonstration waiver is to evaluate the effect that the provision of outpatient prescription drug coverage has on the health status of low-income elderly and disabled populations. New Jersey hypothesizes that the provision of clinically essential medications will allay the deterioration of health among these populations by preventing exacerbation of chronic illnesses. The corollary to this is that the Medicaid program will control costs as there will be savings realized by the delay of this populations' transition to spend-down status for Medicaid eligibility as well as the delay in the need of long term care services.

The following research questions may be explored through this Demonstration Waiver:

Health Status: What impact does the Demonstration have on the health status and quality of care of Demonstration participants?

The health of demonstration participants is expected to improve as they are more likely to obtain prescriptions of clinically essential medications, thereby allaying deterioration of their health. Moreover, the increased use of these medications should help to prevent exacerbation of the multiple chronic illnesses experienced by this population; such as hypertension and diabetes. A more comprehensive coverage plan, and policies that limit medication costs, may help reduce medication restriction and with it the clinical, economic, and social morbidity that disproportionately affects our most vulnerable citizens.

The evaluation of the PAAD demonstration waiver could measure the impact of the demonstration on the health status of participants by examining the following data sources: Medicaid and Medicare Claims Data; and, Case Study Interviews, Focus Groups and Surveys.

Utilization of Resources: Does the Demonstration program design alter the use of other types of services obtained by Demonstration participants? (e.g. decrease nursing home utilization)

This demonstration waiver would help to evaluate whether there is a reduction in the utilization of non-pharmacy services for program participants, as a result of the increased access to clinically essential medications. The demonstration waiver design should cause a shift in the types of services obtained by the Demonstration participants. It is expected that the rate of hospital and nursing home admissions will diminish, a decreased length of stay in hospitals will take place, and decreased utilization of emergency rooms and other medical services will occur. The following sources will be analyzing Medicaid and Medicare Claims Data.

Health Care Policy: Does the Demonstration affect the development of State and Federal health policy, including changes to Medicare and Medicaid?

The Demonstration would allow evaluations of the following: (1) would a federal Medicare prescription drug benefit affect State Medicaid expenditures?; (2) Can State-based assistance programs, if expanded, be sufficient to cover Medicare beneficiaries without prescription drug coverage? If not, what other expansions might be needed and how should they be structured and funded?; (3) What is the effect of cost-sharing arrangements on beneficiary enrollment, including the issue of “crowd out”?; and, (4) What measures to increase quality of care and reduce medication errors is suggested by the Demonstration? Evaluating these issues will allow federal policymakers to make informed decisions regarding a drug benefit as part of a broader reform of Medicare.

Is the Demonstration cost-effective to Medicaid? To Medicare?

Evaluation of Cost-Effectiveness of the Plan – Monitoring Budget Neutrality - See Attached

In order to track expenditures under this Demonstration, the State will report expenditures through:

Quarterly Expenditure Report: The State will provide quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided under the Medicaid program, including those provided through the demonstration under section 1115 authority. This report shall include (1) Report through the Medicaid and State Children’s Health Insurance Program Budget and Expenditure System (MBES/CBES); 2. Form CMS-64.9 Waiver and/ or 64.9P Waiver; and (3) Form CMS-37 The State will estimate matchable Medicaid expenditures on the quarterly Form CMS-37. As a supplement to the Form CMS-37, the State will provide updated estimates of expenditures subject to the budget neutrality cap.